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Saegis Pharmaceuticals Completes Phase IIa Clinical Study of SGS518

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HALF MOON BAY, Calif., Dec. 15 /PRNewswire/ -- Saegis Pharmaceuticals, Inc., a biopharmaceutical company focused on developing medicines that protect and enhance memory and cognition, announced the successful completion of a Phase IIa clinical study of SGS518. Results from the study were presented at The American College of Neuropsychopharmacology Annual Meeting. SGS518, a novel antagonist for the 5HT6 subtype of the serotonin receptor, is being developed as a treatment for Cognitive Impairment Associated with Schizophrenia (CIAS).

The objective of this Phase IIa study was to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of oral doses of SGS518 compared to placebo when given to schizophrenia patients stable on antipsychotic medication. The efficacy measure for cognitive changes during the course of treatment was the Brief Assessment of Cognition in Schizophrenia (BACS) developed by Richard Keefe, Ph.D. at Duke University Medical Center. The placebo-controlled, blinded study was conducted at the Claghorn-Lesem Clinic

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in Houston, Texas.

A total of 20 patients aged 18 to 55 years of age with a DSM-IV diagnosis of stable schizophrenia were enrolled in the study. Patients were randomized into one of two dose-escalating cohorts of 10 subjects each (8 active:2 placebo) and remained in residence for 15 days. Patients were randomized to receive either a low dose-escalating regimen (60/180 mg), a high dose- escalating regimen (120/240 mg) or placebo. The total duration of treatment was 14 days. Cognition testing using the computerized BACS test was conducted prior to dosing, Day 6 prior to escalation and after receipt of the last dose on Day 13. The total duration of treatment was 14 days.

SGS518 demonstrated dose proportionality with steady state reached within 3 days. Multiple doses of up to 240 mg of SGS518 administered once daily were generally well tolerated and did not cause dose-limiting or significant toxicities. A dose response pattern of improvement observed in the BACS endpoint demonstrated statistical significance at the high dose and no effect in the placebo group. SGS518 appears to be safe and well tolerated with preliminary evidence suggesting improvement in cognition using the BACS in patients with schizophrenia.

"This study of a serotonin 5HT6 antagonist demonstrated safety in stable schizophrenic patients," said Rodney Pearlman, Ph.D., President and CEO of Saegis. "Additionally, the BACS as an efficacy endpoint has shown some encouraging data which will provide valuable direction for our ongoing Phase II clinical program. Currently, there are few, if any, therapies available for individuals suffering from Cognitive Impairment Associated with Schizophrenia and we are continuing our efforts to evaluate the efficacy of SGS518 in this patient population. It is hoped that a safe and effective treatment for the cognitive impairment in schizophrenia will help patients lead more normal and productive lives."

SGS518 is a selective antagonist of the 5-Hydroxytryptamine-6 (5-HT6) serotonin receptor believed to act by enhancing transmission of chemicals in the brain. Prior preclinical evaluation of SGS518 has shown it to be effective in behavioral studies of learning and memory. Saegis is developing SGS518 in cooperation with Eli Lilly and Company as a treatment for CIAS with some support from The Stanley Medical Research Institute. Schizophrenia affects an estimated two million people in the United States and a large proportion of these patients are believed to also suffer from cognitive impairment. While currently marketed drugs are often effective in treating the psychoses that characterizes schizophrenia, CIAS remains a significant unmet need, preventing controlled patients from leading normal lives.

About Saegis Pharmaceuticals

Saegis Pharmaceuticals is a pioneer in the development of medicines that protect and enhance the function of the human mind. Saegis is building a portfolio of compounds for the treatment of neurological conditions that impact memory and cognition, including Alzheimer's disease, adult attention deficit hyperactivity disorder (ADHD), mild cognitive impairment and Cognitive Impairment Associated with Schizophrenia (CIAS). Two of the company's orally-available small molecule compounds have demonstrated efficacy and safety in human clinical studies. Saegis' product pipeline is fueled by the discovery and identification of high-value leads leveraging comparative modeling technology of age-related cognitive decline, coupled with the strategic

in-licensing and repositioning of promising clinical-stage compounds. Privately held, Saegis has received investment support from Versant Ventures, Technology Partners, Sofinnova Ventures (U.S.), Sofinnova Partners (Paris), Polaris Venture Partners, NeuroVentures, the Stanley Medical Research Institute and Novartis Pharma AG. For more information, visit www.saegispharma.com.

SOURCE Saegis Pharmaceuticals, Inc. -0- 12/15/2005 /CONTACT: Rodney Pearlman of Saegis Pharmaceuticals, Inc., +1-650-560-0210, ext. 225, or rpearlman@saegispharma.com; or Karen L. Bergman, +1-650-575-1509, or Michelle Corral, +1-415-794-8662, both of BCC Partners, for Saegis Pharmaceuticals, Inc./ /Web site: http://www.saegispharma.com / CO: Saegis Pharmaceuticals, Inc. ST: California IN: BIO MTC HEA SU: TRI JP-ND -- SFTH022 – 7428 12/15/2005 08:30 EST http://www.prnewswire.com

1 of 1

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